

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions, and listings, of claims in the application.

1. (Currently Amended) An essentially anhydrous pharmaceutical composition for oral administration ~~which is directly orally administered without liquid and without chewing~~, comprising at least one pharmaceutical active ingredient in an effective amount and comprising coated particles which have a core containing the at least one pharmaceutical active ingredient, and have a coating consisting of one or more layers, wherein

(a) the coating layer or the coating layers contain at least one hydratable, pharmaceutically acceptable ionic polymer with a viscosity, measured as 1% strength (weight/weight) aqueous solution at 25°C, of from 3 to 30,000 mPa·s and selected from the group consisting of sodium carboxymethylcellulose, sodium carboxymethyl starch, polyacrylic acid, polyacrylate, alginic acid, alginate, pectin, xanthan, galactomannan, guar gum, hydroxypropyl-guar gum, gelatin and gum arabic, which, on contact with saliva, forms a consistent, coherent, soft, mouldable, viscous particle paste in which the particles are stuck together, which is slippery on the surface and does not adhere to the oral mucosa, and which prevents active ingredient-containing particles escaping from the particle paste, and release of active ingredient in the mouth, and

(b) the coating layer or the outermost of the coating layers contains a salivation-promoting agent selected from water-soluble organic acids, sodium hydrogen tartrate, potassium hydrogen tartrate and sodium hydrogen citrate in an amount which is effective, upon said oral administration of the composition, in promoting a flow of saliva which is sufficient to form said coherent, mouldable, viscous particle paste within less than 20 seconds.

2. (Currently Amended) The composition according to claim 1, which furthermore comprises as a hydratable polymer ~~a nonionic polymer with a viscosity, measured as 1% strength (weight/weight) aqueous solution at 25°C, of from 3 to 10,000 mPa·s or an ionic polymer with a viscosity, measured as 1% strength (weight/weight) aqueous solution at 25°C, of from 3 to 30,000 mPa·s~~.

3. (Canceled)

4. (Previously Presented) The composition according to claim 1, which comprises a hydratable polymer with a viscosity, measured as 1% strength (weight/weight) aqueous solution at 25°C, of at least about 25 mPa·s.

5. (Previously Presented) The composition according to claim 1, wherein the hydratable polymer has an average particle size not exceeding 200 µm.

6. (Previously Presented) The composition according to claim 1, wherein the coating is present in an amount of from 5 to 75% by weight, based on the essentially anhydrous composition.

7. (Previously Presented) The composition according to claim 1, which comprises as pharmaceutical active ingredient loperamide, mesalazine, olsalazine, cimetidine, ranitidine, famotidine, nizatidine, omeprazole, sucralfate, pantoprazole, pancreatin, bisacodyl, lactulose, acetylsalicylic acid, paracetamol, ibuprofen, morphine, tramadol, naproxen, diclofenac, piroxicam, terfenadine, astemizole, ambroxol, acetylcysteine, theophylline, atenolol, nifedipine, diltiazem, verapamil, isosorbide mononitrate, amitriptyline, nitrazepam, budesonide, ciprofloxacin, norfloxacin, ofloxacin, amoxicillin, cefaclor, cefadroxil, tetracycline, erythromycin, a pharmaceutically acceptable salt of one of these active ingredients, or a combination of two or more of these active ingredients and salts.

8. (Canceled)

9. (Currently Amended) The composition according to claim 1, which comprises as the salivation-promoting agent tartaric acid, citric acid, malic acid, ascorbic acid, ~~a sodium or potassium salt of these acids, glucose, fructose, sucrose, xylitol, mannitol, sorbitol, maltitol~~ or a combination of two or more of these compounds.

10. (Previously Presented) The composition according to claim 1, wherein the coating consists of two or more layers, and the viscosity, measured as 1% strength (weight/weight) aqueous solution at 25°C, of the hydratable polymer in a layer of the coating is in each case no greater than the viscosity, measured as 1% strength (weight/weight) aqueous solution at 25°C, of the hydratable polymer in the adjacent inner layer of the coating.

11. (Previously Presented) The composition according to claim 10, wherein the outermost layer of the coating comprises a hydratable polymer with a viscosity of from 25 to 5,000 mPa·s, and the second outermost layer of the coating comprises a nonionic hydratable polymer with a viscosity of from 5,000 to 10,000 mPa·s and/or an ionic hydratable polymer with a viscosity of from 5,000 to 30,000 mPa·s, where the viscosities in each case relate to the viscosity of a 1% strength (weight/weight) aqueous solution of the polymer measured at 25°C.

12. (Previously Presented) The composition according to claim 10, wherein the outermost layer of the coating comprises polyvinylpyrrolidone or a cellulose ether with a viscosity of from 25 to 5,000 mPa·s, and the second outermost layer of the coating comprises sodium carboxymethylcellulose with a viscosity of from 5,000 to 8,000 mPa·s, polyacrylic acid with a viscosity of from 5,000 to 30,000 mPa·s or a cellulose ether with a viscosity of from 5,000 to 10,000 mPa·s, where the viscosities in each case relate to the viscosity of a 1% strength (weight/weight) aqueous solution of the polymer measured at 25°C.

13. (Previously Presented) The composition according to claim 10, wherein a hydratable polymer with an average particle size not exceeding 50 μm is used in the second outermost layer of the coating.

14. (Previously Presented) The composition according to claim 10, wherein the second outermost layer of the coating is present in an amount of from 0.25 to 50% by weight, calculated as essentially anhydrous layer and based on the essentially anhydrous active ingredient-containing core, and the outermost layer of the coating is present in an amount of from 3 to 60% by weight, calculated as essentially anhydrous layer and based on the essentially anhydrous composition.

15. (Previously Presented) The composition according to claim 10, wherein the core has a taste-masking coating layer which is resistant to gastric fluid or delays the release of active ingredient.

16. (Previously Presented) The composition according to claim 1, wherein the coated particles have a maximum diameter of from 0.25 to 12 mm.

17-22. (Canceled)

23. (Previously Presented) A medicinal product pack comprising a pharmaceutical composition according to claim 1 and the instructions that the composition be taken by direct administration into the mouth without liquid and without chewing.

24. (Canceled)

25. (Currently Amended) A pharmaceutical composition for oral administration, comprising at least one pharmaceutical active ingredient in an effective amount and comprising coated particles which have a core containing the at least one pharmaceutical active ingredient, and have a coating consisting of one or more layers, wherein

(a) the coating layer or the coating layers contain at least one hydratable, pharmaceutically acceptable ionic polymer with a viscosity, measured as 1% strength (weight/weight) aqueous solution at 25°C, of from 3 to 30,000 mPa·s and selected from the group consisting of sodium carboxymethylcellulose, carboxymethyl starch, polyacrylic acid, polyacrylate, alginic acid, alginate, pectin, xanthan, galactomannan, guar gum, hydroxypropyl-guar gum, gelatin and gum arabic, which, on contact with saliva, forms a consistent, coherent, soft, mouldable, viscous particle paste in which the particles are stuck together, which is slippery on the surface and does not adhere to the oral mucosa, and which prevents active ingredient-containing particles escaping from the paste, and release of active ingredient in the mouth, and

(b) the coating layer or the outermost of the coating layers contains an effective amount of at least one salivation-promoting agent selected from the group consisting of malic acid, ascorbic acid, tartaric acid, sodium hydrogen tartrate, potassium hydrogen tartrate and sodium hydrogen citrate, a sodium or potassium salt of these acids, glucose, xylitol, mannitol, sorbitol, maltitol or and a combination of two or more of these compounds.